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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/081,617	02/21/2002	Steffen Panzner	101215-81	9573

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NORRIS, MCLAUGHLIN & MARCUS, P.A.
875 THIRD AVE
18TH FLOOR
NEW YORK, NY 10022

EXAMINER

KISHORE, GOLLAMUDI S

ART UNIT PAPER NUMBER

1615

DATE MAILED: 08/19/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/081,617

Applicant(s)

PANZNER ET AL.

Examiner

Gollamudi S. Kishore, Ph.D

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 02 June 2005.
- 2a) ☒ This action is FINAL. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-3,5-13 and 22 is/are pending in the application.
- 4a) Of the above claim(s) 12,13 and 21 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-3,5-11 and 22 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date 5-3-05.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

DETAILED ACTION

The amendment dated 5-3-05 and the supplemental response and affidavit dated 6-2-05 are acknowledged.

1. Claim 21 is objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim, namely claim 8. Claim 21 is not completely recited. It ends with 'an average size of. Since the limitations are unclear, it is withdrawn from consideration.

The claims included in the prosecution are 1-3, 5-11 and 22.

Claim Rejections - 35 USC § 102

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

3. Claims 1-3 and 8 are rejected under 35 U.S.C. 102(a) or (b) as being anticipated by Hafez (Biophysical Journal, vol. 79, September 2000, pp. 1438-1446).

Hafez discloses large unilamellar liposomes containing cholesteryl hemisuccinate (CHEMS) and DODAC. The pH values are from 4 to 6.7. The sizes of the liposomes are either 153 ± 34 nm or 274 nm depending upon the ratios of DODAC and CHEMS (abstract, Materials and Methods and Results).

The 102 (b) rejection will be withdrawn upon submission of the English

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translations of the German priority document.

Claim Rejections - 35 USC § 103

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

5. Claims 9-11, and 22 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hafez cited above.

The teachings of Hafez have been discussed above. What is lacking in Hafez is the inclusion of the active agents in the liposomes. However, in the Discussion section (page 1449, col. 1), Hafez suggests the applicability of the liposomes for the delivery of nucleic acids and therefore, it would have been obvious to one of ordinary skill in the art to encapsulate an active agent in the liposomes of Hafez with a reasonable expectation of success. Hafez is also lacking in the teachings of instant sizes between 60 and 130 nm. However, in the absence of showing the criticality, it is deemed obvious to one of ordinary skill in the art to prepare liposomes of desired sizes depending upon the goal by manipulating the sonicating conditions. Furthermore, Hafez also teaches that the liposomal sizes can be varied by varying the ratios of the lipids and the liposomal sizes of 153 with a standard deviation of 34 ($153-34 = 119$) fall within the sizes claimed in instant claim 22.

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6. Claims 1-3, 5-11, and 22 are rejected under 35 U.S.C. 103(a) as being unpatentable over Deshmukh et al (6,258,792).

Deshmukh while disclosing cationic cholesteryl derivatives teaches that while formulating liposomes these cationic cholesterol derivatives may be combined with DOTAP, cholesterol hemisuccinate and neutral lipids such as DOPE. The biologically active agents include DNA, RNA or proteins. The liposome sizes are between 100 and 200 nm. (Abstract, col. 4, line 45 through col. 6, line 6, col. 7, line 41 through col. 8, line 50, col. 10, Examples). It would have been obvious to one of ordinary skill in the art to prepare liposomes containing both cationic lipid and the anionic cholesterol hemisuccinate based on the suggestion of Deshmukh et al. The liposomes of Deshmukh et al would show the same isoelectric point since Deshmukh is suggestive of the same components and provide guidance for the preparation of liposomes with a reasonable expectation of success.

7. Claims 5-11, and 22 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hafez cited above, in view of Deshmukh cited above.

The teachings of Hafez have been discussed above. What are lacking in Hafez are the teachings of the inclusion of another lipid and the inclusion of an active agent. Deshmukh as pointed out above, teaches that a neutral lipid can be included in the liposomes containing a cationic lipid and CHEMS. Deshmukh also teaches the use of these liposomes for the delivery of active agents such as DNA, RNA and proteins. It would have been obvious to one of ordinary skill in the art to include a neutral lipid or encapsulate active agents such as nucleic acids or proteins in the liposomes of Hafez

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with a reasonable expectation of success since Deshmukh teaches that neutral lipids can be included in the liposomes and these liposomes can be used to encapsulate nucleic acids and proteins.

Applicant's arguments and the declaration have been fully considered, but are deemed to be moot in view of the new rejection.

8. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Gollamudi S Kishore, Ph.D whose telephone number is

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(571) 272-0598. The examiner can normally be reached on 6:30 AM- 4 PM, alternate Friday off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman K Page can be reached on (571) 272-0602. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Gollamudi S Kishore, Ph.D
Primary Examiner
Art Unit 1615

GSK